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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/058,696	01/28/2002	Roland Stoughton	9301-168-999	5433

7590

06/13/2005

JONES DAY  
222 EAST 41 ST STREET  
NEW YORK, NY 10017

EXAMINER
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ALLEN, MARIANNE P

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 06/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/058,696

Applicant(s)

STOUGHTON ET AL.

Examiner

Marianne P. Allen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 14, 15, 20, 21, 23, 25-27, 43-82 and 95-132 is/are pending in the application.
- 4a) Of the above claim(s) 45-54, 61, 62 and 95-132 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14, 15, 20, 21, 23, 25-27, 43-44, 55-60, and 63-82 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 14, 15, 20, 21, 23, 25-27, 43-82 and 95-132 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicant's arguments filed 3/29/05 have been fully considered but they are not persuasive.

Claims 14-15, 20-21, 23, 25-27, 43-82, and 95-132 are pending.

#### ***Election/Restrictions***

Claims 45-54 and 61-62 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected species (perturbation elected was exposure to a pharmacological agent and organism type elected was *Homo sapien*), there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 6/21/04.

Newly submitted claims 95-132 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 95-112 are directed to a method with steps and goals different than the method of claim 14. Claims 113-130 are directed to a method with steps and goals different than the method of claim 14. Claims 131-132 are directed to a method with steps and goals different than the method of claim 14. None of these methods have been previously presented or considered.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 95-132 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 14-15, 20-21, 23, 25-27, 43-44, 55-60, and 63-82 are under consideration by the examiner.

***Double Patenting***

Claims 14-15, 20-21, 23, 25-27, 43-44, 55-60, and 63-82 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14-27 of copending Application Nos. 11/042,653 and 11/042,654. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and co-pending claims are directed to the same methods with overlapping embodiments.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 112***

Claims 14-15, 20-21, 23, 25-27, 43-44, 55-60, and 63-82 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 15 is directed to a computer system comprising a processor and a memory encoding one or more programs coupled to the processor. The programs cause the processor to perform a particular method. Claims 44, 56, 58, 60, 64, 66, 68, 70, 72, 74, 76, 79-82 are dependent upon claim 15. These claims are confusing in their dependency on claim 15.

Claim 44 adds the limitation as to how the perturbation is performed.

Claims 56, 58, and 60 identify the biological system.

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Claims 64 and 66 designate the baseline state of the biological system.

Claims 68, 70, 72, 74, and 76 define the microarray composition.

Claims 79-82 describe the experiment, including type of fluorophore.

None of these dependent claims further modifies the computer system. The processor, memory, and/or programs are not modified by these limitations. Note that the program is not changed, customized, or adapted for any of these particular features. That is, a user loads the differential microarray experimental data (however produced) into the computer system. The execution of the software programs analyzes the data. (See for example, section 5.8 on computer implementations.) For example, the computer system is not particularly adapted for human versus yeast data or for microarrays containing 100 genes versus 200 genes.

The steps of the method of claim 14 and executed by the computer system of claim 15 are confusing as written. Part (a) requires “determining an error distribution statistic by fitting a reference pair of microarray experiments with an intensity independent statistic.” This is confusing because an experiment is not fitted. Data of some variety from an experiment (e.g. fluorescent signals) could be fitted but it is unclear what is meant by fitting an experiment. The claims goes on to recite in part (a) “according to a formula.” It is unclear whether the formula represents the error distribution statistic, the intensity independent statistic that must then be fitted to give the error distribution statistic, or something else.

Part (b) requires “determining...an amount of change in expression level...using said error distribution statistic.” It is unclear what one of ordinary skill in the art is supposed to do to meet this limitation. That is, the error distribution statistic is not the amount of change and the

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claims do not make clear how the error distribution statistic is to be applied or used to provide the amount of change.

Part (c) requires “determining said probability...by combining...each amount of change...determined in step (b) using a rank based method. The formulas that follow represent the chance that the cellular constituent is **not** up-regulated or is **not** down-regulated. This is confusing as it is the opposite of the intent of the method (i.e. determining the probability that the cellular constituent is altered by a perturbation). It is unclear what one of ordinary skill in the art is supposed to do to meet the limitation of part (c). Is “using a rank based method comprising” intended to indicate that the computation of  $P(H^+)$  or  $P(H^-)$  is all that is necessary or are further steps required and, if so, what are they?

Applicant is cautioned against introducing new matter into the claims.

### ***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712. The examiner can normally be reached on Monday-Thursday, 5:30 am - 1:30 pm.

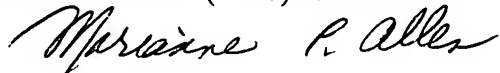
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the

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problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



Marianne P. Allen  
Primary Examiner  
Art Unit 1631

6/8/05

mpa